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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,351	01/31/2001	Daniel H. Maes	00.22US	5974

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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/773,351

Applicant(s)

MAES ET AL.

Examin r

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 February 2003.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) Claim(s) 1 and 3-20 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 3-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 - If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 - * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on February 5, 2003 in Paper No. 20 wherein claims 1, 16, and 18-19 have been amended and claim 2 is cancelled. Currently, claims 1 and 3-20 are pending in this application.

Applicant's amendment amending claim 1 filed on February 5, 2003 in Paper No. 20 with respect to the rejection of claims 1-12 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expression, i.e., "effective amounts" in claims 1, of record stated in the Office Action dated November 5, 2002 have been fully considered and found persuasive to remove this particular rejection since the phrase "effective amounts" has been deleted from the claims.

Applicant's amendment amending claims 16 and 19 filed on February 5, 2003 in Paper No. 20 with respect to the rejection of claims 16-20 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expression "applying said mixture to the skin" in claims 16 and 19, of record stated in the Office Action dated November 5, 2002 have been fully considered and found persuasive to remove this particular rejection.

Applicant's amendment amending claim 18 filed on February 5, 2003 in Paper No. 20 with respect to the rejection of claim 18 made under 35 U.S.C. 112 second paragraph for the lack of antecedent in claim 18, of record stated in the Office Action dated November 5, 2002 have been fully considered and found persuasive to remove this particular rejection since the claimed range has been amended.

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Applicant's amendment changing the limitation to a specific range of amounts of actives herein in claim 1 filed on February 5, 2003 in Paper No. 20 with respect to the rejection of claims 1, 3, and 11 made under 35 U.S.C. 102(b) as being anticipated by Ribier et al. (5,925,364) for reasons of record stated in the Office Action dated November 5, 2002 have been considered and are found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

The following is a new rejection necessitated by Applicant's amendment filed on February 5, 2003 in Paper No. 20, wherein the limitations in the claims amended as now have been changed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 6-9, 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,925,364, of record) in view of Sebag et al.(5,411,742, of record).

Ribier et al. discloses a cosmetic or dermatological composition comprising the ionic amphiphilic lipid such as the alkali metal salts of cholesterol sulphate in particular

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the sodium salt in amount of 2-6% by weight preferably 3-4% by weight (see col.3 lines 43-48 and 54-55, col.4 lines 12-15), salicylic acid (a known exfoliant) (see claim 18 at col.15 line 6), keratolytic agents (known exfoliants) (see col.5 line 36, claim 15 at col.14 line 49), fatty acids (see col.4 line 60, claim 18 at col.15 line 5), and Centella asiatica extract (see col.4 line 64, claim 18 at col.15 line 8).

Ribier et al. does not expressly disclose the employment of the particular fatty acid, linoleic acid, and cholesterol in the composition herein. The prior art does also not expressly disclose the amounts of an exfoliant in the composition herein.

Sebag et al. discloses a cosmetic or dermatological composition comprising the salts of cholesterol (see col.2 line 34), salicylic acid or its derivatives (known exfoliants) in amounts of 3-10% by weight (see abstract, col.3 lines 26-36), keratolytic agents (known exfoliants) (see col.6 line 66), the particular fatty acid, linoleic acid (see claim 10 at col.17 line 17), and cholesterol (see claim 8 at col.17 lines 5-6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular fatty acid, linoleic acid, and cholesterol in the composition of Ribier and to optimize the effective amounts of an exfoliant in the composition herein to about 10% by weight.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular fatty acid, linoleic acid, and cholesterol in the composition of Ribier since fatty acids broadly and the particular fatty acid, linoleic acid, are known to be useful in a cosmetic or dermatological for of treating skin based on the prior art. Moreover, cholesterol is well known to be used a cosmetic or

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dermatological for of treating skin according Sebag. Therefore, one of ordinary skill in the art would have reasonably expected that combining the composition of Ribier and the composition of Sebag known useful for the same purpose, treating skin, in a composition to be administered would improve the therapeutic effect for treating skin.

Since all active composition components herein are known to useful to treat skin, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of the alkali metal salts of cholesterol sulphate and an exfoliant in the composition because their amounts are known in the art and the optimization of known amounts of active agents to be administered is considered well within the skill of artisan. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's arguments filed on February 5, 2003 in Paper No. 20 with respect to this rejection of claims 1, 3, and 11 made under 35 U.S.C. 102(b) as being anticipated by Ribier et al. (5,925,364) for reasons of record stated in the Office Action dated

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November 5, 2002 have been considered but are moot in view of the new ground(s) of rejection above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-9, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,650,166) for reasons of record stated in the Office Action dated November 5, 2002.

Applicant's remarks filed on February 5, 2003 in Paper No. 20 with respect to this rejection made under 35 U.S.C. 103(a) of record stated in the Office Action dated November 5, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Again, Applicant argument that the '166 reference fails to teach or suggest a mixture of cholesterol sulfate and an exfoliant of the present invention, is not found convincing since Ribier '166 discloses that the composition therein comprises cholesterol sulfate (col.3 lines 66-67 in particular) and N-acetylglucosamine (NADG, the instant exfoliant) (see col.5 line 67).

In response to applicant's argument that that the '166 reference are contrary to the present invention because with the mixture of NADG and cholesterol sulfate there is

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no separation or vehicle, it is noted that the features upon which applicant relies (i.e., the mixture of NADG and cholesterol sulfate there is no separation or vehicle) are not recited in the rejected claim(s). Therefore, it is irrelevant whether the reference includes those features or not. Moreover, separating NADG and cholesterol sulfate in a known composition or adding the mixture to a vehicle is considered well within the skill of artisan, involving merely routine skill in the art.

Claims 10-12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,650,166) further in view of Subbiah (6,150,381) and Ichinose et al. (5,702,691) for reasons of record stated in the Office Action dated November 5, 2002.

Applicant's remarks filed on February 5, 2003 in Paper No. 20 with respect to this rejection made under 35 U.S.C. 103(a) of record stated in the Office Action dated November 5, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. The motivation to combine the teachings of the prior art cited herein to make the present invention has been clearly discussed in the previous Office Action.

Further, Applicant's one Example shown in the specification at pages 8-10 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art for the reasons below. Example 1 provides no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no comparison to the same present. Therefore, the evidence presented in specification herein is not seen to be

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clear and convincing in support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry-concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

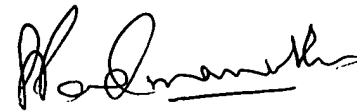
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 29, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

5/4/03